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XP-000980708

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Rolling therapeutic agent loading device for therapeutic agent delivery or coated stent

P. d. 06-2000

Stents are typically implanted within a vessel to maintain vessel integrity in order to allow fluid flow through the vessel. Balloon catheters are often utilized to implant the stent in the vessel. These devices as well as other devices used in body passageways can be coated with a pharmacologically active substance for either short or long term local delivery to the passageway. The method described can be used for loading a therapeutic agent onto a device used in a blood vessel.

In this process, as shown in Fig. 1, an anchoring fixture, such as a spiral mandrel or a hypotube (A) is securely fitted and inserted into a vessel device (B), such as, but not limited to, a stent. This will secure the vessel device on the anchoring fixture during the therapeutic agent loading process. The device (B) is pre-coated with a swell-loading or therapeutic agent specific "binding" polymer. By rolling the stent on a carrier (C) such as, but not limited to, a cloth or sponge, soaked with either a therapeutic agent solution or a tacky therapeutic agent paste (D); the therapeutic agent is loaded into the polymer.

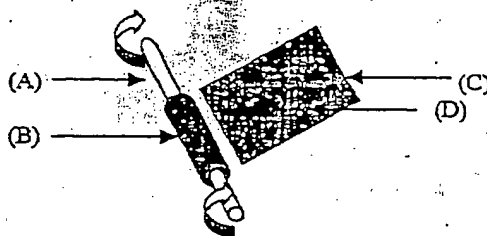


Fig. 1

When the operator loads the therapeutic agent solution or tacky paste (D) onto the vessel device (B), the vessel device (B) mounted on the anchoring fixture (A) is rotated forward on either a therapeutic agent soaked carrier (C and D) or a tacky therapeutic agent paste (D). In the embodiment using the tacky therapeutic agent paste (D), a binding agent can be added to the raw therapeutic agent material to cause adhesion of the therapeutic agent powder particles. This anchoring fixture (A) and method will allow the cardiologist to load therapeutic agent solution or tacky therapeutic agent paste (D) onto the vessel device (B) prior to deployment into the patient. This method eliminates the complexity of preloaded therapeutic agent delivery devices, such as stents. This invention allows the cardiologist the freedom to choose whichever therapeutic agent thought to be beneficial to the patient.

The anchoring device (A) may be made from any number of materials. Examples include, but are not limited to, polytetrafluoroethylene (PTFE), polypropylene, polymethylmethacrylate (PMMA), stainless steel or glass. The swell loading or therapeutic agent specific "binding" polymer which is precoated onto the device (B) may include, but is not limited to, the following: polyethyleneglycol (PEG), hydroxyethylmethacrylate (HEMA),

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polyvinylpyrrolidone (PVP), x-linked hyaluronic acid based hydrogels for swell loading; polycaprolactone (PCL), polylactic acid (PLA), polyglycolic acid (PGA), and copolymers thereof; biopolymers, elastin, or collagen elastin. The therapeutic agent solution or tacky therapeutic agent paste (D) may consist of, but are not limited to the following: therapeutic agent in a single suspension, single solution, or in solution with a polymer that acts as a matrix. Possible polymers and copolymer components include, but are not limited to the following: ethylene vinyl alcohol (EVAL) and polyurethanes.

In an alternative embodiment as shown in Fig. 2, the therapeutic agent solution (D) can be loaded onto the vessel device (B) by rotating the anchoring fixture (A), on which the vessel device (B) is secured onto, in a cylindrical cup (E) filled with therapeutic agent solution. The cup is lined with a carrier (C) such as, but not limited to, a sponge or foam type material soaked with therapeutic agent solution (D). The vessel device (B) is rolled along the inside wall of the therapeutic agent (D) soaked carrier (C) thereby loading the vessel device (B) with the therapeutic agent solution (D). The cup (E) may be made from any non-reactive substance such as, but not limited to, plastic or glass.

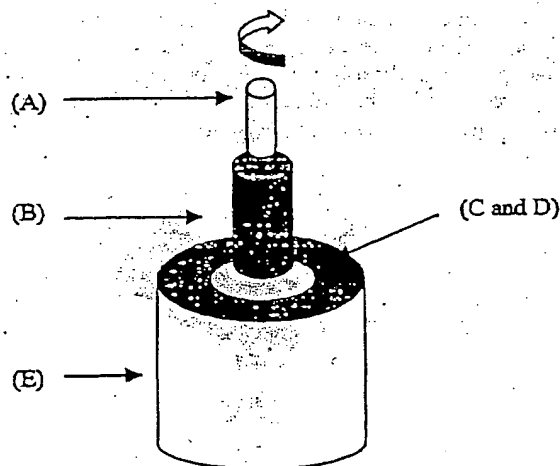


Fig. 2

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